DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAR 29 2007

Re: Vusion
Docket No. 2007E-0035

The Honorable Jon Dudas
Under Secretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 4,911,932 filed by Johnson and Johnson Consumer Companies, Inc. under 35 U.S.C. § 156. The human drug product claimed by the patent is Vusion (miconazole nitrate/zinc oxide/white petrolatum), which was assigned new drug application (NDA) No. 21-026.

A review of the Food and Drug Administration's (FDA's) official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). Our records also indicate that two of the active ingredients in Vusion (miconazole nitrate and zinc oxide) do not represent the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1), and interpreted by the courts in *Glaxo Operations UK Ltd. v. Quigg*, 706 F. Supp. 1224 (E.D. Va. 1989), *aff'd*, 894 F. 2d 392 (Fed. Cir. 1990). We have no record that the third ingredient of Vusion, white petrolatum, has been previously approved under section 505 of the Federal Food, Drug, and Cosmetic Act as an active ingredient in a drug product, but it has been approved for commercial marketing as an inactive ingredient in drug products approved under section 505.

The NDA was approved on February 16, 2006, which makes the submission of the patent term extension application on April 5, 2006, timely within the meaning of 35 U.S.C. § 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the *Federal Register*, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely yours,

ENTERED
3/27/07

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research